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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/7981,583 | 02/03/98 | DICKMANNS | A 028622/070 |

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HM12/0921

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| EXAMINER |
| HARRIS, A |

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|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 1642 | 13 |

DATE MAILED: 09/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|--|---|
| Application No. 08/981,583 | Applicant(s) Dickmanns et al. |
| Examiner Alana M. Harris, Ph. D. | Group Art Unit 1642 |

Responsive to communication(s) filed on _____.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 0 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-37 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-37 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, 16-22, 29-31, 33, and 34 are drawn to an immortalized epithelial tumor cell and to an *in vitro* process for the production of a transformed cell, classified in class 435, subclasses 371 and 467. Claims 33 and 34 will be examined to the extent that they read on a pharmaceutical composition comprising epithelial tumor cells.
 - II. Claims 13-15 and 32-33, are drawn to an antibody molecule and kits containing said antibody, classified in class 530, subclass 387.7. Claims 33 and 34 will be examined to the extent that they read on a pharmaceutical composition comprising an antibody molecule.
 - III. Claim 35, drawn to a method of treating by administering a pharmaceutical composition comprising the epithelial tumor cell, classified in class 424, subclass 93.1. Claim 35 will be examined with Group III to the extent that it reads on the administration of a tumor cell.
 - IV. Claim 35, drawn to a method of treating by administering a pharmaceutical composition comprising an antibody molecule, classified in class 424, subclass 130.1. Claim 35 will be examined with Group IV to the extent that it reads on the administration of an antibody molecule.

Art Unit:

- V. Claim 36, is drawn to a treatment method comprising *ex vivo* stimulating immune cells, classified in class 514, subclass 44.
- VI. Claim 37, is drawn to a method of diagnosing or detecting, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups III-VI differ in the method objectives, method steps and parameters and in the reagents used.

Inventions of Group I and of Group III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the immortalized epithelial tumor cell of Group I can be used in *in vitro* diagnostic methods.

Inventions of Group II and of Groups IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

Art Unit:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody molecule of Group II can be used in the 2 different methods of IV and VI.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Attempts to reach Stephen Bent by telephone on 9/14/99 to request an oral election to the above restriction requirement were unsuccessful.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Art Unit:

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, whose telephone number is (703) 306-5880.



Nancy A Johnson
Primary Examiner